4.0 STUDY DESIGN

4.1 Overview

This is a randomized, double-blind, placebo-controlled, multi-institutional Phase II study. There is no washout period and no cross-over. Patients taking anti-retroviral medication at study entry must have a 90-day acclimatization period on their drug prior to treatment with test article. Study subjects will be stratified both by absolute $CD4^+$ T cell count (100-249 cells/mm^3, 250-399 cells/mm^3, ≥400 cells/mm^3) and use of an anti-retroviral agent at study entry (yes/no). The randomization will be unbalanced by a 2:1 ratio in favor of active treatment for subjects with fewer than 400 $CD4^+$ T cells. The treatment phase of the study will last 2 years. During the treatment interval use of reverse transcriptase inhibitors is restricted because of a potential interaction with the mode of action of the study drug. Reverse transcriptase inhibitors are not allowed for 96 hours (4 days) prior to each dose of test article and for 48 hours (2 days) after each dose (6 days total). Otherwise, subjects will receive the standard of medical care for HIV infection and concomitant conditions, including anti-infective prophylaxis at the investigator's option. Subjects will be monitored for study endpoints at defined intervals in the study. The level of CTL activity against HLA-matched allogeneic target cells which express ENV antigen will be determined in approximately half of the subjects by restricting the monitoring to selected study sites.

4.2 Number of Subjects

Approximately 190 subjects will be treated in this study in up to 16 clinical sites nationwide. Subjects will be enrolled within a 3 month time span at each clinical site. Subjects who do not complete 2 courses of treatment and evaluation as defined in the protocol will be replaced. Enrollment will be skewed based on $CD4^+$ count (Table 1).